

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMNISURE INTERNATIONAL, LLC, and N-DIA, INC.,	)	
	)	
Plaintiffs	)	
	)	
v.	)	Civil Action No.
	)	
ALL DIAG S.A. and BIOSYNEX,	)	
	)	
Defendants	)	
	)	

## COMPLAINT AND JURY DEMAND

## INTRODUCTION

1. Plaintiffs developed, own, manufacture and sell a medical device known as AmniSure (“AmniSure”), which is used for the diagnosis of the premature rupture of fetal membranes. They own certain copyrights in connection with AmniSure. Defendant All Diag S.A. (“All Diag”) was formerly a licensed distributor of AmniSure until the distribution agreement was terminated by the Plaintiffs as a result of breaches by All Diag. Both prior to and after the termination of the distribution agreement, All Diag engaged in conduct which infringed upon Plaintiffs’ AmniSure copyrights and constituted, among other things, unfair competition and tortious interference with AmniSure’s advantageous business relations. All Diag engaged in that conduct directly and/or through agents, including Defendant Biosynex which is under joint ownership and/or control with All Diag. Plaintiffs seek the following: injunctive relief and damages resulting from Defendants’ copyright infringement; damages for tortious interference and unfair competition; and damages for breach of contract and breach of the covenant of good faith and fair dealing.

**PARTIES**

2. Plaintiff Amnisure International, LLC (“AI”) is a limited liability company organized and existing pursuant to the laws of the Commonwealth of Massachusetts, with its principal place of business at 30 JFK Street, Cambridge, MA 02138. AI is a citizen of the Commonwealth of Massachusetts.

3. Plaintiff N-Dia, Inc. (“N-Dia”) is a corporation organized and existing pursuant to the laws of the State of New Jersey, with its principal place of business located at 30 JFK Street, Cambridge, MA 02138. N-Dia is a citizen of the State of New Jersey and the Commonwealth of Massachusetts.

4. Defendant All Diag, S.A. (“All Diag”), upon information and belief, is a Société par actions simplifiée organized and existing pursuant to the laws of France, with its principal place of business located at 10 Rue Ettore Bugatti, 67038 Strasbourg, France. All Diag is a citizen of France. Thomas Lamy (“Lamy”), upon information and belief, is President of All Diag and has an ownership interest in All Diag. Thierry Paper (“Paper”), upon information and belief, is the Director of Research and Development at All Diag and has an ownership interest in All Diag.

5. Defendant Biosynex, upon information and belief, is a Société à responsabilité limitée organized and existing pursuant to the laws of France, with its principal place of business located at 12 Rue Ettore Bugatti, 67038 Strasbourg, France. Biosynex is a citizen of France. Lamy, upon information and belief, is a Co-Manager of Biosynex and has an ownership interest in Biosynex. Paper, upon information and belief, is a Co-Manager of Biosynex and has an ownership interest in Biosynex.

**JURISDICTION AND VENUE**

6. Subject matter jurisdiction of this Court is invoked pursuant to 28 U.S.C. §§ 1331, 1338(a), as it is an action arising under Acts of Congress relating to copyrights, namely, the Federal Copyright Act of 1976, 17 U.S.C. §101 et seq. Subject matter jurisdiction as to the non-copyright claims is based on both: (a) supplemental jurisdiction pursuant to 28 U.S.C. § 1367; and (b) diversity jurisdiction pursuant to 28 U.S.C. § 1332(a)(2) in that this action is between plaintiff citizens of the Commonwealth of Massachusetts and the State of New Jersey and defendant citizens of France, and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

7. Personal jurisdiction over Defendants, upon information and belief, is established pursuant to:

(a) Mass. Gen. Laws ch. 223A, § 3(a) based on the continuous and systematic activity, and purposeful availment, of the Defendants, directly and/or through any agent, in this Commonwealth; and/or Plaintiffs' claims arising, in part or in whole, from the Defendants' transaction of business, directly and/or through any agent, in this Commonwealth; and/or

(b) Mass. Gen. Laws ch. 223A, § 3(d) in that the Defendants caused tortious injury in this Commonwealth by an act or omission outside this Commonwealth and, directly and/or through any agent, regularly do or solicit business, and engage in other persistent course of conduct in this Commonwealth, and, directly and/or through any agent, derive substantial revenue from goods used or services rendered in this Commonwealth; and, in the alternative,

(c) Fed. R. Civ. P. 4(k)(2) based on the Defendants' contacts with the United States, to the extent that the Defendants are not subject to personal jurisdiction in any state's courts of general jurisdiction.

8. Venue in the District of Massachusetts is pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District.

**ALLEGATIONS COMMON TO ALL CLAIMS**

9. N-Dia is in the business of developing, manufacturing and selling medical diagnostic devices and products. N-Dia develops diagnostic products based on its research in the field of cellular biotechnology. N-Dia's products utilize proprietary monoclonal antibodies against specific proteins that are associated with particular diseases or medical conditions. N-Dia has developed a method that allows diagnostic devices to detect very small quantities of substances that are indicative of a disease or medical condition, which permits early and accurate detection and the possibility of timely treatment.

10. N-Dia developed, owns, manufactures and sells AmniSure which is a device for the diagnosis of the premature rupture of fetal membranes ("PROM"). PROM occurs when a woman's amniotic fluid breaks prematurely and is not followed by labor within 24-48 hours. PROM occurs in about 10% of pregnant women and constitutes the major factor in pre- and post-natal morbidity and mortality. At least 30% of pregnant women are checked for PROM.

11. AmniSure was the first product on the market to provide an easy-to-use and accurate diagnosis of PROM. AmniSure is a rapid, accurate and non-invasive strip test that gives a positive or negative answer in a few minutes.

12. Beginning in or about 2003, N-Dia and All Diag began discussing the possibility of entering into a distribution relationship whereby All Diag would serve as distributor of AmniSure in France. These discussions resulted in an oral agreement in May 2003 which was memorialized shortly thereafter in an exchange of e-mails. On or about August 25, 2004, an additional written agreement (the "2004 Agreement") was signed by N-Dia, as the supplier, and

All Diag, as the distributor. Subsequent to the execution of the 2004 Agreement, N-Dia and All Diag continued to engage in communications which further defined their distribution relationship. The foregoing oral and written agreements are collectively referred to herein as the “Distribution Agreement.”

13. It was an essential term of the Distribution Agreement that All Diag was appointed as distributor in the territory of France only. All Diag was granted no distribution rights outside of the territory of France. On information and belief, All Diag was at all times aware that N-Dia had granted the distribution rights for territories outside of France to other distributors.

14. Through the distribution relationship, All Diag demanded that N-Dia sell AmniSure to All Diag at a price substantially lower than the price level typically given by N-Dia to other distributors of AmniSure in other territories. An important element of the marketing strategy of AmniSure worldwide is to maintain price levels appropriate to, and reflective of, AmniSure’s status as the “gold standard” of PROM testing. All Diag, however, insisted that N-Dia give All Diag substantially reduced pricing, claiming that price reductions were necessary for All Diag to be successful in launching AmniSure in France. At All Diag’s insistence, throughout the duration of the relationship, N-Dia gave All Diag pricing that was substantially lower than that given to other distributors of AmniSure elsewhere in the world, including in other European countries.

15. All Diag also insisted on selling AmniSure under the name “Amnitop” in France. All Diag represented to N-Dia that the name “AmniSure” (which is a U.S. registered trademark) would be unattractive to French customers and not conducive to sales in France. The name “Amnitop” was selected by All Diag to be consistent with other products sold by All Diag (such

as “Rhumatop,” “Tetanotop” and “Vrstop”). Initially, N-Dia acceded to All Diag’s demand based on All Diag’s representations about the French response to the name “AmniSure.”

16. At all times during the existence of the distribution relationship, the product sold by All Diag under the name “Amnitop” was N-Dia’s product AmniSure. AmniSure (Amnitop) was (and is) manufactured in Massachusetts.

17. In or about June 2005, N-Dia entered into a license agreement (the “Amnisure License”) with AI. Pursuant to the Amnisure License, N-Dia granted AI certain rights with respect to AmniSure.

18. Thereafter, AI took over N-Dia’s role in the distribution relationship with All Diag. From that point forward, All Diag’s relationship was conducted exclusively with AI in Massachusetts. All Diag sent purchase orders for AI’s products to AI in Massachusetts. AI, from its Massachusetts location, submitted invoices to All Diag. All invoices submitted to All Diag indicated that AI was located in Massachusetts. All Diag wired payments directly to AI’s bank account located in Massachusetts. AI shipped the requested product from Massachusetts to All Diag.

19. On information and belief, All Diag was at all times aware that AI was located in Massachusetts. For example, on one occasion when the parties agreed to meet in person, the All Diag representative went to Boston for the meeting (even though the AI representative had told him that he would meet with the All Diag representative at a conference in New York).

20. Beginning in May 2006, AI began requesting that All Diag cease using the name “Amnitop” and switch to the mark “AmniSure” in connection with AmniSure, for the purpose of enhancing brand name awareness. All Diag failed or refused to do so, and continued to market AmniSure under the name “Amnitop.”

21. Upon information and belief, during the existence of the distribution relationship, All Diag engaged in unauthorized sales and promotion of AmniSure (under the name “Amnitop”) in territories outside of France, including in Spain, Portugal, Switzerland, Benelux, and Turkey. All Diag did not disclose to N-Dia or AI that it was engaged in such sales outside of its authorized territory. When confronted by AI, All Diag denied that it was engaging in unauthorized extra-territorial sales, or misrepresented the extent of its extra-territorial activities.

22. Upon information and belief, Biosynex was created in or about March 2005. Upon information and belief, All Diag and Biosynex are under common ownership and/or control, as well as common management. Lamy is President of, and has an ownership interest in, All Diag, and is a Co-Manager of, and has an ownership interest in, Biosynex. Paper is Director of Research and Development of, and has an ownership interest in, All Diag, and is a Co-Manager of, and has an ownership interest in, Biosynex.

23. Upon information and belief, during the existence of the distribution relationship, Biosynex began manufacturing a product that directly competes with AmniSure (Amnitop). Biosynex manufactures this product under the name “Amnioquick” although it is also marketed and sold under other names, including “Pro-M” (in the United States), “Amniodetect” and “Nadal.” Amnioquick is a test for PROM that is virtually identical to AmniSure in the manner in which it is used by the customer, but it is an inferior test and relies on different technology (it detects a different protein (IGFBP-1) than the protein detected by AmniSure (PAMG-1)).

24. Upon information and belief, during the existence of the distribution relationship, All Diag began contacting current and prospective distributors of AI in an effort to sell them Amnioquick.

25. Upon information and belief, All Diag and Biosynex created and distributed

packaging, package inserts and marketing materials for Amnioquick that contain unauthorized and unfair copying of the corresponding AmniSure (Amnitop) materials, and which are confusingly similar to the AmniSure (Amnitop) materials.

26. On or about October 16, 2008, AI notified All Diag that it was terminating the distribution relationship based on the numerous breaches by All Diag, acting on behalf of itself, through agents and/or through Biosynex. The grounds for termination included, without limitation, the following:

- (a) unauthorized distribution of AmniSure in multiple markets outside of France;
- (b) solicitation of current and potential distributors of AmniSure with offers for Amnioquick;
- (c) the creation and distribution of packaging, package inserts and marketing materials for Amnioquick that contain unauthorized and unfair copying of the corresponding AmniSure materials, and which are confusingly similar to such materials;
- (d) All Diag's refusal to market AmniSure under the "AmniSure" trademark; and
- (e) failure to achieve promised sales results.

27. On or about October 30, 2008, All Diag released a notice announcing a new rapid diagnostic test for PROM under the name "Amnitop Optima." On information and belief, "Amnitop Optima" is Amnioquick.

28. On information and belief, after the termination of the distribution relationship, All Diag began filling orders for Amnitop with Amnitop Optima instead.



29. On information and belief, the packaging, package inserts and marketing materials for “Amnitop Optima,” like those of Amnioquick, also contain unauthorized and unfair copying of the corresponding AmniSure (Amnitop) materials, and are confusingly similar to the AmniSure (Amnitop) materials.

30. All Diag’s website continues to advertise Amnitop, not Amnitop Optima, and does not disclose that All Diag is now supplying Amnitop Optima and that Amnitop Optima is a different product produced by a different manufacturer that tests for a different protein.

31. On information and belief, customers of AmniSure (Amnitop) have been confused and deceived into believing that the product being sold to them by All Diag is AmniSure (Amnitop), or a new version thereof, when in fact it is Amnioquick/Amnitop Optima—an inferior product that examines a different protein in testing for PROM. On information and belief, customers have been disappointed with the performance of Amnioquick/Amnitop Optima, which has tarnished AmniSure’s reputation and goodwill.

**COUNT I**  
**(Copyright Infringement – Preliminary & Permanent Injunctive Relief)**

32. Plaintiffs repeat the allegations of the foregoing paragraphs and incorporate them by reference as if fully set forth herein.

33. In or about 2003, the employees of N-Dia authored packaging, package inserts and marketing materials for AmniSure, including but not limited to the package insert attached hereto as Exhibit A (“Plaintiffs’ Package Insert 1”).

34. Plaintiffs’ Package Insert 1 is a work made for hire and constitutes copyrightable subject matter under the laws of the United States.

35. AI, as the assignee of N-Dia’s copyright rights, is the owner of a valid copyright registration for Plaintiffs’ Package Insert 1, Registration Number TX 6-977-966. A copy of the

Certificate of Registration for Plaintiffs' Package Insert 1 is attached hereto as Exhibit B.

36. In or about 2009, the employees of N-Dia authored packaging, package inserts and marketing materials for AmniSure, including but not limited to the package insert attached hereto as Exhibit C ("Plaintiffs' Package Insert 2").

37. Plaintiffs' Package Insert 2 is a work made for hire and constitutes copyrightable subject matter under the laws of the United States.

38. AI, as the assignee of N-Dia's copyright rights, is the owner of a valid copyright registration for Plaintiffs' Package Insert 2, Registration Number TX 6-977-941. A copy of the Certificate of Registration for Plaintiffs' Package Insert 2 is attached hereto as Exhibit D.

39. The Plaintiffs own Plaintiffs' Package Inserts 1 and 2 and the exclusive copyrights therein and are entitled to copyright protection.

40. Defendant All Diag, acting on behalf of itself, through agents and/or through Defendant Biosynex, produces and markets one or more products that compete with Amnisure.

41. In conjunction with the marketing of the competing product(s), Defendant All Diag, acting on behalf of itself, through agents and/or through Defendant Biosynex, uses package inserts and other product materials (collectively, "Defendants' Product Materials"), including, but not limited to, the package inserts attached hereto as Exhibit E & Exhibit F.

42. Defendant All Diag and Defendant Biosynex, which is owned and/or controlled by the same individuals that own and/or control All Diag, had access to Plaintiffs' Package Inserts 1 and 2.

43. Defendant All Diag, acting on behalf of itself and/or through Defendant Biosynex, knowingly, willfully, intentionally and maliciously, copied in their entirety substantial parts of Plaintiffs' Package Inserts 1 and 2, and then used Defendants' Product Materials

containing the copied material to offer for sale and sell their competing product(s).

44. All Diag, acting on behalf of itself, through agents and/or through Defendant Biosynex, has solicited orders, marketed and/or distributed a product or products competing with AmniSure and in conjunction therewith used Defendants' Product Materials containing the copied material.

45. On information and belief, Defendants' Product Materials, including the infringing package inserts, have been distributed to prospective customers in Massachusetts.

46. Defendants have usurped Plaintiffs' unique and valuable copyrights in Plaintiffs' Package Inserts 1 and 2 without obtaining a license from Plaintiffs for such use.

47. By means of the foregoing acts and practices, Defendant All Diag, acting on behalf of itself, through agents and/or through Defendant Biosynex, has committed copyright infringement under 17 U.S.C. § 501 *et seq.* which is substantially injurious and detrimental to Plaintiffs' copyrights and business.

48. By reason of the foregoing acts and practices, Plaintiffs are entitled to a preliminary and permanent injunction prohibiting both Defendants from any and all acts of copyright infringement against the Plaintiffs.

**COUNT II**  
**(Copyright Infringement – Damages)**

49. Plaintiffs repeat the allegations of the foregoing paragraphs and incorporate them by reference as if fully set forth herein.

50. By means of the foregoing acts and practices, Defendant All Diag, acting on behalf of itself, through agents and/or through Defendant Biosynex, has committed copyright infringement which is substantially injurious and detrimental to Plaintiffs' copyrights and business.

51. By reason of the foregoing acts and practices, Plaintiffs have suffered damages in an amount to be determined at the trial of this action.

**COUNT III**  
**(Tortious Interference With Advantageous Business Relations)**

52. Plaintiffs repeat the allegations of the foregoing paragraphs and incorporate them by reference as if fully set forth herein.

53. The Plaintiffs had advantageous business relationships with distributors and customers for the Plaintiffs' product, AmniSure.

54. On information and belief, the Defendants have intentionally interfered with those relationships.

55. The Defendants' interference was wrongful in motive or means.

56. The Plaintiffs have been damaged by the Defendants' interference in an amount be determined at trial.

**COUNT IV**  
**(Common Law Unfair Competition )**

57. Plaintiffs repeat the allegations of the foregoing paragraphs and incorporate them by reference as if fully set forth herein.

58. The Defendants have marketed and sold Amnioquick by means of acts and practices that (a) would tend to confuse medical professionals and the public as to the source and origin of Amnioquick and (b) falsely suggest that Amnioquick is AmniSure (Amnitop) and/or is related to AmniSure (Amnitop). The Defendants' acts and practices of unfair competition include, but are not limited to, the following: the use of confusingly similar product names; the use of confusingly similar marketing materials and package inserts; and the use of misleading advertising on the internet.

59. In marketing and selling Amnioquick, the Defendants attempted (and still are attempting) to deceive the public into believing it was (and is) dealing with the Plaintiffs when in fact it was (and is) dealing with the Defendants.

60. The Defendants' actions have been committed knowingly in order to capitalize on and misappropriate the Plaintiffs' valuable goodwill associated with AmniSure (Amnitop).

61. As a result of the Defendants' actions as alleged herein, the Plaintiffs have suffered and will continue to suffer damage and injury to their business, reputation and goodwill.

62. Unless enjoined by this Court, the Defendants will continue their unfair competition. The Defendants' unfair competition has and will continue to cause irreparable harm to the Plaintiffs for which they have no adequate remedy at law.

63. As a result of the Defendants' acts alleged above, the Plaintiffs are entitled to a preliminary and permanent injunction prohibiting both Defendants from any and all acts of unfair competition against the Plaintiffs.

64. As a result of the Defendants' acts alleged above, the Plaintiffs are entitled to damages in an amount to be proven at trial.

**COUNT V**  
**(Breach of Contract – Damages)**

65. Plaintiffs repeat the allegations of the foregoing paragraphs and incorporate them by reference as if fully set forth herein.

66. The Distribution Agreement constituted a valid and enforceable contract between the Plaintiffs and All Diag.

67. By means of the foregoing acts and practices committed during the existence of the Distribution Agreement, Defendant All Diag, acting on behalf of itself, through agents and/or through Defendant Biosynex, breached the Distribution Agreement.

68. Plaintiffs fully performed their obligations, if any, under the Distribution Agreement.

69. By reason of the foregoing acts and practices, Plaintiffs have suffered damages in an amount to be determined at trial.

**COUNT VI**  
**(Breach Of Duty Of Good Faith & Fair Dealing – Damages)**

70. Plaintiffs repeat the allegations of the foregoing paragraphs and incorporate them by reference as if fully set forth herein.

71. The duty of good faith and fair dealing is an implied term of the Distribution Agreement, whereby neither party shall do anything that will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract.

72. By means of the foregoing acts and practices, Defendant All Diag, acting on behalf of itself, through agents and/or through Defendant Biosynex, breached the duty of good faith and fair dealing implicit in the Distribution Agreement.

73. By reason of the foregoing acts and practices, Plaintiffs have suffered damages in an amount to be determined at trial.

**WHEREFORE**, Plaintiffs pray that judgment be granted in their favor, including, but not limited to:

- A. Enter judgment for the Plaintiffs on all Counts of the Complaint;
- B. Enter a preliminary injunction enjoining the Defendants, and their agents, employees and anyone acting in concert with them, during the pendency of this Action, from infringing the aforesaid copyrights of Plaintiffs in any manner, and from publishing, licensing, selling, marketing and/or otherwise disposing of any copies of the infringing Defendants' Product Materials; and requiring Defendants to deliver up, to be impounded during the pendency of this action, all copies of marketing materials, package inserts and packaging and any and all other

documents, in written or electronic or any other form, containing the infringing Defendants' Product Materials in their possession or under their control, and to deliver up for destruction all infringing copies and all other matter for making such infringing copies;

- C. Enter a permanent injunction at the conclusion of this action enjoining the Defendants, and their agents, employees and anyone acting in concert with them, from infringing the aforesaid copyrights of Plaintiffs in any manner, and from publishing, licensing, selling, marketing and/or otherwise disposing of any copies of the infringing Defendants' Product Materials; and requiring Defendants to deliver up to the Plaintiffs all copies of marketing materials, package inserts and packaging and any and all other documents, in written or electronic or any other form, containing the infringing Defendants' Product Materials in their possession or under their control, and to deliver up for destruction all infringing copies and all other matter for making such infringing copies;
- D. Enter a preliminary injunction and, at the conclusion of this Action, a permanent injunction, enjoining the Defendants, and their agents, employees and anyone acting in concert with them, from engaging in acts of unfair competition, including the use of confusingly similar marketing materials and package inserts, and confusingly similar product names and misleading website advertising;
- E. Enter an award on Count II:
  - (i) granting the Plaintiffs such actual damages as Plaintiffs have sustained as a result of Defendants' copyright infringement pursuant to 17 U.S.C. § 504(b); and
  - (ii) requiring both Defendants to account for and disgorge to Plaintiffs all gains, profits, and advantages derived by Defendants from their infringement of Plaintiffs' copyrights, pursuant to 17 U.S.C. 504(c);
- F. Enter an award of damages on Counts III-VI in an amount to be proven at trial;
- G. Enter an award of Plaintiffs' costs, interest and attorneys' fees incurred in connection with this action; and
- H. Grant such other and further relief in favor of Plaintiffs as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

The Plaintiffs hereby demand a trial by jury on all claims so triable.

Respectfully Submitted,

AMNISURE INTERNATIONAL, LLC and  
N-DIA, INC.,

By Their Attorneys,

s/ Julie E. Green

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